

Message

From: Doug Spilker [doug.spilker@bayer.com]
Sent: 6/14/2018 3:57:40 PM
To: Breeden-Alemi, Julie [Breeden-Alemi.Julie@epa.gov]
CC: Aubee, Catherine [Aubee.Catherine@epa.gov]; Davis, Kable [Davis.Kable@epa.gov]; IVB1 [IVB1@epa.gov]; Will Heeb [will.heeb@bayer.com]; Rick Kingston (rkingston@safetycall.com) [rkingston@safetycall.com]
Subject: RE: Incident Severity Code meeting of 3/26/18

Flag: Follow up

Dear Dr. Breeden-Alemi:

We would like to again thank the Agency for the in-person discussion regarding our mutual interest in further clarifying incident severity categorization for the sake of consistency and harmonization. Will Heeb, Rick Kingston and I are especially thankful for the time and further thoughtful consideration to the input provided by the attendees. The Agency's feedback regarding separating the animal and human categorization guides was particularly helpful and we believe it further enhances the utility of the documents for our surveillance teams as we move forward.

The consideration of practices of other organizations is an important reminder as to the complexity of the task at hand and the varying ways in which data is currently being categorized and analyzed. We hope the efforts we have put into harmonizing our internal practices can also be helpful to future industry-wide discussions involving the Agency and other organizations. To this end, we look forward to sharing our experience in this important area and continued collaboration with the Agency and others.

Best regards,

Doug

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From: Breeden-Alemi, Julie [mailto:Breeden-Alemi.Julie@epa.gov]
Sent: Monday, May 14, 2018 2:35 PM
To: Doug Spilker
Cc: Aubee, Catherine; Davis, Kable; IVB1
Subject: Incident Severity Code meeting notes from 3/26/18

Good afternoon Doug,

EPA appreciates the efforts set forth to facilitate consistency in understanding and defining incident severity categories as presented in the meeting that took place on 3/26/18. The following input has been compiled from the attendees as requested. We hope that this input is helpful moving forward.

1. Guidelines should consider practices established by AAPCC-NPDS and FDA-FAERS and CDC/NIOSH SENSOR-Pesticides. To the extent definitions are harmonized, that should help improve consistency across organizations involved with adverse event monitoring and reporting.
2. PRN 98-3 addresses humans separately from animals. The presented document combines humans and animals. While the combination may serve to simplify matters in some respects, there are also some disadvantages in doing so. For example, behavioral symptoms/clinical signs/indicators cannot always be interpreted the same way for humans and animals.
3. Consideration as to severity categorization of behavioral and neurological symptoms/clinical signs/indicators may require additional attention. For example, paresthesia, twitching, and transient incoordination/ataxia (currently noted in the presented document under minor, but not specifically in PRN 98-3) could be difficult for an individual to distinguish from a partial seizure especially in an animal and could indicate a more significant neurological complication. In PRN 98-3 for animals behavioral examples provided include agitation and hyperactivity which could be interpreted as physical indicators as a reaction to the application of a product (for example, surprise of a cold liquid hitting the skin) vs. those that can indicate a more significant neurological effect. Another point of consideration is that some of the behavioral/neurological clinical signs listed in under the minor category can be interpreted as markers for permethrin toxicity in cats.
4. Consider re-evaluation of examples provided for each category (minor, moderate, major) to determine placement in the appropriate category. Patient follow-up and how that affects such placement presents a noted challenge as discussed.
5. Here are links to the documents, mentioned during the 3/26/18 meeting, that are used by the SENSOR-Pesticides program participants to determine and code human case severity. These include examples of adverse health signs and symptoms for each level of severity. The SENSOR state coordinators are trained by CDC/NIOSH on how to properly code for severity to "ensure uniformity" of severity coding across states. Then there is biannual QA/QC on case coding; including severity.

<https://www.cdc.gov/niosh/topics/pesticides/pdfs/pest-sevindexv6.pdf>

<https://www.cdc.gov/niosh/topics/pesticides/pdfs/pest-sitablev6.pdf>

<https://www.cdc.gov/niosh/topics/pesticides/pdfs/pest-sevflow6.pdf>

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